JUNE 13, 2018

RULES COMMITTEE PRINT 115–76

TEXT OF H.R. 6, SUBSTANCE USE-DISORDER PREVENTION THAT PROMOTES OPIOID RECOVERY AND TREATMENT FOR PATIENTS AND COMMUNITIES ACT

[Showing the text of H.R. 6, as introduced]

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act'' or the ''SUPPORT for Patients and Communities Act''.

(b) TABLE OF CONTENTS.—The table of contents for the Act is as follows:

TITLE I—MEDICAID PROVISIONS TO ADDRESS THE OPIOID CRISIS

SEC. 101. AT-RISK YOUTH MEDICAID PROTECTION.

(a) IN GENERAL.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—

(1) in subsection (a)—

(A) by striking ''and'' at the end of paragraph (82);

(B) by striking the period at the end of paragraph (83) and inserting ''; and''; and

(C) by inserting after paragraph (83) the following new paragraph:

''(84) provide that—

''(A) the State shall not terminate eligibility for medical assistance under the State plan for an individual who is an eligible juvenile (as defined in subsection (nn)(2)) because the juvenile is an inmate of a public institution (as defined in subsection (nn)(3)), but may suspend coverage during the period the juvenile is such an inmate;

''(B) in the case of an individual who is an eligible juvenile described in paragraph (2)(A) of subsection (nn), the State shall, prior to the individual's release from such a public institution, conduct a redetermination of eligibility for such individual with respect to such medical assistance (without requiring a new application from the individual) and, if the State determines pursuant to such redetermination that the individual continues to meet the eligibility requirements for such medical assistance, the State shall restore coverage for such medical

assistance to such an individual upon the individual's release from such public institution; and

''(C) in the case of an individual who is an eligible juvenile described in paragraph (2)(B) of subsection (nn), the State shall process any application for medical assistance submitted by, or on behalf of, such individual such that the State makes a determination of eligibility for such individual with respect to such medical assistance upon release of such individual from such public institution.''; and

(2) by adding at the end the following new subsection:

''(nn) JUVENILE; ELIGIBLE JUVENILE; PUBLIC INSTITUTION.—For purposes of subsection (a)(84) and this subsection:

''(1) JUVENILE.—The term 'juvenile' means an individual who is—

''(A) under 21 years of age; or

''(B) described in subsection (a)(10)(A)(i)(IX).

''(2) ELIGIBLE JUVENILE.—The term 'eligible juvenile' means a juvenile who is an inmate of a public institution and who—

''(A) was determined eligible for medical assistance under the State plan immediately before becoming an inmate of such a public institution; or

''(B) is determined eligible for such medical assistance while an inmate of a public institution.

''(3) INMATE OF A PUBLIC INSTITUTION.—The term 'inmate of a public institution' has the meaning given such term for purposes of applying the subdivision (A) following paragraph (29) of section 1905(a), taking into account the exception in such subdivision for a patient of a medical institution.''.

(b) NO CHANGE IN EXCLUSION FROM MEDICAL ASSISTANCE FOR INMATES OF PUBLIC INSTITUTIONS.—Nothing in this section shall be construed as changing the exclusion from medical assistance under the subdivision (A) following paragraph (29) of section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)), including any applicable restrictions on a State submitting claims for Federal financial participation under title XIX of such Act for such assistance.

(c) NO CHANGE IN CONTINUITY OF ELIGIBILITY BEFORE ADJUDICATION OR SENTENCING.—Nothing in this section shall be construed to mandate, encourage, or sug-

gest that a State suspend or terminate coverage for individuals before they have been adjudicated or sentenced.

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by subsection (a) shall apply to eligibility of juveniles who become inmates of public institutions on or after the date that is 1 year after the date of the enactment of this Act.

(2) RULE FOR CHANGES REQUIRING STATE LEGISLATION.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be

deemed to be a separate regular session of the State legislature.

SEC. 102. HEALTH INSURANCE FOR FORMER FOSTER YOUTH.

(a) COVERAGE CONTINUITY FOR FORMER FOSTER CARE CHILDREN UP TO AGE 26.—

(1) IN GENERAL.—Section 1902(a)(10)(A)(i)(IX) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(i)(IX)) is amended—

(A) in item (bb), by striking ''are not described in or enrolled under'' and inserting ''are not described in and are not enrolled under'';

(B) in item (cc), by striking ''responsibility of the State'' and inserting ''responsibility of a State''; and

(C) in item (dd), by striking ''the State plan under this title or under a waiver of the'' and inserting ''a State plan under this title or under a waiver of such a''.

(2) EFFECTIVE DATE.—The amendments made by this subsection shall take effect with respect to foster youth who attain 18 years of age on or after January 1, 2023.

(b) GUIDANCE.—Not later than one year after the date of the enactment of this Act, the Secretary of Health

and Human Services shall issue guidance to States, with respect to the State Medicaid programs of such States—

(1) on best practices for—

(A) removing barriers and ensuring streamlined, timely access to Medicaid coverage for former foster youth up to age 26; and

(B) conducting outreach and raising awareness among such youth regarding Medicaid coverage options for such youth; and

(2) which shall include examples of States that have successfully extended Medicaid coverage to former foster youth up to age 26.

SEC. 103. DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY UNDER THE MEDICAID PROGRAM.

Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by adding at the end the following new subsection:

''(aa) DEMONSTRATION PROJECT TO INCREASE SUBSTANCE USE PROVIDER CAPACITY.—

''(1) IN GENERAL.—Not later than the date that is 180 days after the date of the enactment of this section, the Secretary shall, in consultation, as appropriate, with the Director of the Agency for Healthcare Research and Quality and the Assistant

Secretary for Mental Health and Substance Use, conduct a 54-month demonstration project for the purpose described in paragraph (2) under which the Secretary shall—

''(A) for the first 18-month period of such project, award planning grants described in paragraph (3); and

''(B) for the remaining 36-month period of such project, provide to each State selected under paragraph (4) payments in accordance with paragraph (5).

''(2) PURPOSE.—The purpose described in this paragraph is for each State selected under paragraph (4) to increase the treatment capacity of providers participating under the State plan (or a waiver of such plan) to provide substance use disorder treatment or recovery services under such plan (or waiver) through the following activities:

''(A) For the purpose described in paragraph (3)(C)(i), activities that support an ongoing assessment of the behavioral health treatment needs of the State, taking into account the matters described in subclauses (I) through (IV) of such paragraph.

''(B) Activities that, taking into account the results of the assessment described in subparagraph (A), support the recruitment, training, and provision of technical assistance for providers participating under the State plan (or a waiver of such plan) that offer substance use disorder treatment or recovery services.

''(C) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that—

''(i) are authorized to dispense drugs approved by the Food and Drug Administration for individuals with a substance use disorder who need withdrawal management or maintenance treatment for such disorder;

''(ii) have in effect a registration or waiver under section 303(g) of the Controlled Substances Act for purposes of dispensing narcotic drugs to individuals for maintenance treatment or detoxification treatment and are in compliance with any regulation promulgated by the Assistant

Secretary for Mental Health and Substance Use for purposes of carrying out the requirements of such section 303(g); and

''(iii) are qualified under applicable State law to provide substance use disorder treatment or recovery services.

''(D) Improved reimbursement for and expansion of, through the provision of education, training, and technical assistance, the number or treatment capacity of providers participating under the State plan (or waiver) that have the qualifications to address the treatment or recovery needs of—

''(i) individuals enrolled under the State plan (or a waiver of such plan) who have neonatal abstinence syndrome, in accordance with guidelines issued by the American Academy of Pediatrics and American College of Obstetricians and Gynecologists relating to maternal care and infant care with respect to neonatal abstinence syndrome;

''(ii) pregnant women, postpartum women, and infants, particularly the con-

current treatment, as appropriate, and comprehensive case management of pregnant women, postpartum women and infants, enrolled under the State plan (or a waiver of such plan);

''(iii) adolescents and young adults between the ages of 12 and 21 enrolled under the State plan (or a waiver of such plan); or

''(iv) American Indian and Alaska Native individuals enrolled under the State plan (or a waiver of such plan).

''(3) PLANNING GRANTS.—

''(A) IN GENERAL.—The Secretary shall, with respect to the first 18-month period of the demonstration project conducted under paragraph (1), award planning grants to at least 10 States selected in accordance with subparagraph (B) for purposes of preparing an application described in paragraph (4)(C) and carrying out the activities described in subparagraph (C).

''(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

''(i) select States that have a State plan (or waiver of the State plan) approved under this title;

''(ii) select States in a manner that ensures geographic diversity; and

''(iii) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

''(C) ACTIVITIES DESCRIBED.—Activities described in this subparagraph are, with respect to a State, each of the following:

''(i) Activities that support the development of an initial assessment of the behavioral health treatment needs of the State to determine the extent to which providers are needed (including the types of such providers and geographic area of need) to improve the network of providers that treat substance use disorders under

the State plan (or waiver), including the following:

''(I) An estimate of the number of individuals enrolled under the State plan (or a waiver of such plan) who have a substance use disorder.

''(II) Information on the capacity of providers to provide substance use disorder treatment or recovery services to individuals enrolled under the State plan (or waiver), including information on providers who provide such services and their participation under the State plan (or waiver).

''(III) Information on the gap in substance use disorder treatment or recovery services under the State plan (or waiver) based on the information described in subclauses (I) and (II).

''(IV) Projections regarding the extent to which the State participating under the demonstration project would increase the number of providers offering substance use disorder treatment or recovery services

under the State plan (or waiver) during the period of the demonstration project.

''(ii) Activities that, taking into account the results of the assessment described in clause (i), support the development of State infrastructure to, with respect to the provision of substance use disorder treatment or recovery services under the State plan (or a waiver of such plan), recruit prospective providers and provide training and technical assistance to such providers.

''(D) FUNDING.—For purposes of subparagraph (A), there is appropriated, out of any funds in the Treasury not otherwise appropriated, $50,000,000, to remain available until expended.

''(4) POST-PLANNING STATES.—

''(A) IN GENERAL.—The Secretary shall, with respect to the remaining 36-month period of the demonstration project conducted under paragraph (1), select not more than 5 States in accordance with subparagraph (B) for purposes of carrying out the activities described in para-

graph (2) and receiving payments in accordance with paragraph (5).

''(B) SELECTION.—In selecting States for purposes of this paragraph, the Secretary shall—

''(i) select States that received a planning grant under paragraph (3);

''(ii) select States that submit to the Secretary an application in accordance with the requirements in subparagraph (C), taking into consideration the quality of each such application;

''(iii) select States in a manner that ensures geographic diversity; and

''(iv) give preference to States with a prevalence of substance use disorders (in particular opioid use disorders) that is comparable to or higher than the national average prevalence, as measured by aggregate per capita drug overdoses, or any other measure that the Secretary deems appropriate.

''(C) APPLICATIONS.—

''(i) IN GENERAL.—A State seeking to be selected for purposes of this paragraph

shall submit to the Secretary, at such time and in such form and manner as the Secretary requires, an application that includes such information, provisions, and assurances, as the Secretary may require, in addition to the following:

''(I) A proposed process for carrying out the ongoing assessment described in paragraph (2)(A), taking into account the results of the initial assessment described in paragraph (3)(C)(i).

''(II) A review of reimbursement methodologies and other policies related to substance use disorder treatment or recovery services under the State plan (or waiver) that may create barriers to increasing the number of providers delivering such services.

''(III) The development of a plan, taking into account activities carried out under paragraph (3)(C)(ii), that will result in long-term and sustainable provider networks under the State plan (or waiver) that will offer

a continuum of care for substance use disorders. Such plan shall include the following:

''(aa) Specific activities to increase the number of providers (including providers that specialize in providing substance use disorder treatment or recovery services, hospitals, health care systems, Federally qualified health centers, and, as applicable, certified community behavioral health clinics) that offer substance use disorder treatment, recovery, or support services, including short-term detoxification services, outpatient substance use disorder services, and evidence-based peer recovery services.

''(bb) Strategies that will incentivize providers described in subparagraphs (C) and (D) of paragraph (2) to obtain the necessary training, education, and support to deliver substance use

disorder treatment or recovery services in the State.

''(cc) Milestones and timeliness for implementing activities set forth in the plan.

''(dd) Specific measurable targets for increasing the substance use disorder treatment and recovery provider network under the State plan (or a waiver of such plan).

''(IV) A proposed process for reporting the information required under paragraph (6)(A), including information to assess the effectiveness of the efforts of the State to expand the capacity of providers to deliver substance use disorder treatment or recovery services during the period of the demonstration project under this subsection.

''(V) The expected financial impact of the demonstration project under this subsection on the State.

''(VI) A description of all funding sources available to the State to provide substance use disorder treatment or recovery services in the State.

''(VII) A preliminary plan for how the State will sustain any increase in the capacity of providers to deliver substance use disorder treatment or recovery services resulting from the demonstration project under this subsection after the termination of such demonstration project.

''(VIII) A description of how the State will coordinate the goals of the demonstration project with any waiver granted (or submitted by the State and pending) pursuant to section 1115 for the delivery of substance use services under the State plan, as applicable.

''(ii) CONSULTATION.—In completing an application under clause (i), a State shall consult with relevant stakeholders, including Medicaid managed care plans, health care providers, and Medicaid bene-

ficiary advocates, and include in such application a description of such consultation.

''(5) PAYMENT.—

''(A) IN GENERAL.—For each quarter occurring during the period for which the demonstration project is conducted (after the first 18 months of such period), the Secretary shall pay under this subsection, subject to subparagraph (C), to each State selected under paragraph (4) an amount equal to 80 percent of so much of the qualified sums expended during such quarter.

''(B) QUALIFIED SUMS DEFINED.—For purposes of subparagraph (A), the term 'qualified sums' means, with respect to a State and a quarter, the amount equal to the amount (if any) by which the sums expended by the State during such quarter attributable to substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan) exceeds 1/4 of such sums expended by the State during fiscal year 2018 attributable to substance use treatment or recovery services.

''(C) NON-DUPLICATION OF PAYMENT.—In the case that payment is made under subparagraph (A) with respect to expenditures for substance use treatment or recovery services furnished by providers participating under the State plan (or a waiver of such plan), payment may not also be made under subsection (a) with respect to expenditures for the same services so furnished.

''(6) REPORTS.—

''(A) STATE REPORTS.—A State receiving payments under paragraph (5) shall, for the period of the demonstration project under this subsection, submit to the Secretary a quarterly report, with respect to expenditures for substance use treatment or recovery services for which payment is made to the State under this subsection, on the following:

''(i) The specific activities with respect to which payment under this subsection was provided.

''(ii) The number of providers that delivered substance use disorder treatment or recovery services in the State under the demonstration project compared to the es-

timated number of providers that would have otherwise delivered such services in the absence of such demonstration project.

''(iii) The number of individuals enrolled under the State plan (or a waiver of such plan) who received substance use disorder treatment or recovery services under the demonstration project compared to the estimated number of such individuals who would have otherwise received such services in the absence of such demonstration project.

''(iv) Other matters as determined by the Secretary.

''(B) CMS REPORTS.—

''(i) INITIAL REPORT.—Not later than October 1, 2020, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an initial report on—

''(I) the States awarded planning grants under paragraph (3);

''(II) the criteria used in such selection; and

''(III) the activities carried out by such States under such planning grants.

''(ii) INTERIM REPORT.—Not later than October 1, 2022, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress an interim report—

''(I) on activities carried out under the demonstration project under this subsection;

''(II) on the extent to which States selected under paragraph (4) have achieved the stated goals submitted in their applications under subparagraph (C) of such paragraph;

''(III) with a description of the strengths and limitations of such demonstration project; and

''(IV) with a plan for the sustainability of such project.

''(iii) FINAL REPORT.—Not later than October 1, 2024, the Administrator of the Centers for Medicare & Medicaid Services shall, in consultation with the Director of the Agency for Healthcare Research and Quality and the Assistant Secretary for Mental Health and Substance Use, submit to Congress a final report—

''(I) providing updates on the matters reported in the interim report under clause (ii);

''(II) including a description of any changes made with respect to the demonstration project under this subsection after the submission of such interim report; and

''(III) evaluating such demonstration project.

''(C) AHRQ REPORT.—Not later than three years after the date of the enactment of this subsection, the Director of the Agency for Healthcare Research and Quality, on consultation with the Administrator of the Centers for

Medicare & Medicaid Services, shall submit to Congress a summary on the experiences of States awarded planning grants under paragraph (3) and States selected under paragraph (4).

''(7) DATA SHARING AND BEST PRACTICES.—During the period of the demonstration project under this subsection, the Secretary shall, in collaboration with States selected under paragraph (4), facilitate data sharing and the development of best practices between such States and States that were not so selected.

''(8) CMS FUNDING.—There is appropriated, out of any funds in the Treasury not otherwise appropriated, $5,000,000 to the Centers for Medicare & Medicaid Services for purposes of implementing this subsection. Such amount shall remain available until expended.''.

SEC. 104. DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.

(a) IN GENERAL.—Title XIX of the Social Security Act is amended by inserting after section 1927 (42 U.S.C. 1396r–8) the following new section:

"SEC. 1927A. DRUG MANAGEMENT PROGRAM FOR AT-RISK BENEFICIARIES.

"(a) IN GENERAL.—Beginning January 1, 2020, a State shall operate a qualified drug management program under which a State may enroll certain at-risk beneficiaries identified by the State under the program.

"(b) QUALIFIED DRUG MANAGEMENT PROGRAM.—For purposes of this section, the term 'qualified drug management program' means, with respect to a State, a program carried out by the State (including through a contract with a pharmacy benefit manager) that provides at least for the following:

"(1) IDENTIFICATION OF AT-RISK INDIVIDUALS.—Under the program, the State identifies, in accordance with subsection (c), individuals enrolled under the State plan (or waiver of the State plan) who are at-risk beneficiaries.

"(2) ELEMENTS OF PROGRAM.—

"(A) IN GENERAL.—Under the program, the State, with respect to each individual identified under paragraph (1) and enrolled under the program under paragraph (5)—

"(i) subject to subparagraphs (B) and (C), selects at least one, but not more than three, health care providers and at least one, but not more than three, pharmacies

for each such individual for purposes of clause (ii), in accordance with a selection process that takes into account reasonable factors such as the individual's previous utilization of items and services from health care providers and pharmacies, geographic proximity of the individual to such health care providers and pharmacies, access of the individual to health care, reasonable travel time, information regarding housing status, and any known preference of the individual for a certain health care provider or pharmacy; and

''(ii) requires that any controlled substance furnished to such individual during the period for which such individual is enrolled under the program be prescribed by a health care provider selected under clause (i) for such individual and dispensed by a pharmacy selected under clause (i) for such individual in order for such controlled substance to be covered under the State plan (or waiver).

''(B) BENEFICIARY PREFERENCE.—In the case of an individual receiving a notice under

paragraph (3)(A) of being identified as potentially being an at-risk beneficiary described in such paragraph, such individual may submit, during the 30-day period following receipt of such notice, preferences for which health care providers and pharmacies the individual would prefer the State to select under subparagraph (A). The State shall select or change the selection of health care providers and pharmacies under subparagraph (A) for the individuals based on such preferences, except that in the case that State determines that such selection (or change of selection) of a health care provider or pharmacy under subparagraph (A) is contributing or would contribute to prescription drug abuse or drug diversion by the individual, the State may select or change the selection of health care provider or pharmacy for the individual without regard to the preferences of the individual described in this subparagraph. If the State selects or changes the selection pursuant to the preceding sentence without regard to the preferences of the individual, the State shall provide the individual with at least 30 days written notice of the selection or change of se-

lection and a rationale for the selection or change.

''(C) TREATMENT OF PHARMACY WITH MULTIPLE LOCATIONS.—For purposes of subparagraph (A)(i), in the case of a pharmacy that has multiple locations that share real-time electronic prescription data, all such locations of the pharmacy shall collectively be treated as one pharmacy.

''(D) TREATMENT OF EXISTING FFS DRUG MANAGEMENT PROGRAMS.—In the case of a patient review and restriction program (as identified in the annual report submitted to the Secretary under section 1927(g)(3)(D)) operated by a State pursuant to section 1915(a)(2) before the date of the enactment of this section, such program shall be treated as a qualified drug management program.

''(E) REASONABLE ACCESS.—The program shall ensure, including through waiver of elements of the program (including under subparagraph (A)(ii)), reasonable access to health care (including access to health care providers and pharmacies with respect to prescription drugs described in subparagraph (A)) in the

case of individuals with multiple residences, in the case of natural disasters and similar situations, and in the case of the provision of emergency services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).

''(3) NOTIFICATION TO IDENTIFIED INDIVIDUALS.—Under the program, the State provides each individual who is identified under paragraph (1), prior to enrolling such individual under the program, at least one notification of each of the following:

''(A) Notice that the State has identified the individual as potentially being an at-risk beneficiary for abuse or misuse of a controlled substance.

''(B) The name, address, and contact information of each health care provider and pharmacy that may be selected for the individual under paragraph (2)(A).

''(C) Information describing all State and Federal public health resources that are designed to address such abuse or misuse to which the individual has access, including mental health services, substance use disorder and recovery services, and other counseling services.

''(D) Notice of, and information about, the right of the individual to—

''(i) submit preferences of the individual for health care providers and pharmacies to be selected under paragraph (2)(A), including as described in paragraph (2)(B);

''(ii) appeal under paragraph (4)—

''(I) such identification described in subparagraph (A); and

''(II) the selection of health care providers and pharmacies under paragraph (2)(A).

''(E) An explanation of the meaning and consequences of the identification of the individual as potentially being an at-risk beneficiary for abuse or misuse of a controlled substance, including an explanation of the program.

''(F) Information, including a contact list and clear instructions, that explain how the individual can contact the appropriate entities administering the program in order to submit preferences described in paragraph (2)(B) and any other communications relating to the program.

''(4) APPEALS PROCESS.—Under the program, the State provides for an appeals process under which, with respect to an individual identified under paragraph (1)—

''(A) such individual may appeal—

''(i) such identification; and

''(ii) the selection of a health care provider or pharmacy under paragraph (2)(A);

''(B) in the case of an appeal described in subparagraph (A)(ii), the State shall accommodate the health care provider or pharmacy preferred by the individual for selection for purposes of paragraph (2)(A), unless the State determines that a change to the selection of health care provider or pharmacy under such paragraph is contributing or would contribute to prescription drug abuse or drug diversion by the individual;

''(C) such individual is provided a period of not less than 30 days following the date of receipt of the notice described in paragraph (3) to submit such appeal; and

''(D) the State must make a determination with respect to an appeal described in subparagraph (A), and notify the individual of such de-

termination, prior to enrollment of such individual in the program.

''(5) ENROLLMENT.—Under the program, the State initially enrolls individuals who are identified under paragraph (1) in the program for a 12-month period—

''(A) in the case of such an individual who does not submit an appeal under paragraph (4) within the period applied by the State pursuant to subparagraph (C) of such paragraph, beginning on the day after the last day of such period; and

''(B) in the case of such an individual who does submit an appeal under paragraph (4) within the period applied by the State pursuant to subparagraph (C) of such paragraph but such appeal is denied, beginning not later than 30 days after the date of such denial.

''(6) NOTIFICATION OF HEALTH CARE PROVIDERS AND PHARMACIES.—Under the program, the State provides to each health care provider and pharmacy selected for an individual under paragraph (2)—

''(A) notification that the individual is an at-risk beneficiary enrolled under the program

and that the provider or pharmacy has been selected for the individual under paragraph (2);

"(B) information on such program and the role of being so selected; and

"(C) a process through which the provider or pharmacy can submit a concern or complaint with respect to being so selected.

"(7) CONTINUATION OF ENROLLMENT.—Under the program, the State, with respect to an individual enrolled under the program, provides for a process to—

"(A) not later than 30 days before the end of the 12-month period for which the individual is so enrolled pursuant to paragraph (5)—

"(i) assess, in accordance with publicly available evidence-based guidelines, whether or not such individual should continue to be enrolled under the program; and

"(ii) notify such individual of the results of the assessment under clause (i);

"(B) continue, subject to subparagraph (C), enrollment of such individual if such assessment recommends such continuation; and

''(C) appeal the continuation of enrollment in accordance with the appeals process described in paragraph (4).

''(c) AT-RISK BENEFICIARY.—

''(1) IDENTIFICATION.—For purposes of this section, a State shall identify an individual enrolled under the State plan (or waiver of the State plan) as an at-risk beneficiary if the individual is not an exempted individual described in paragraph (2) and—

''(A) is identified as such an at-risk beneficiary through the use of publicly available evidence-based guidelines that indicate misuse or abuse of a controlled substance; or

''(B) the State received notification from a PDP sponsor or Medicare Advantage organization that such individual was identified as being an at-risk beneficiary for prescription drug abuse for enrollment in a drug management program established by the sponsor or organization pursuant to section 1860D–4(c)(5) and such identification has not been terminated under subparagraph (F) of such section.

''(2) EXEMPTED INDIVIDUAL DESCRIBED.—For purposes of paragraph (1), an exempted individual described in this paragraph is an individual who—

''(A) is receiving—

''(i) hospice or palliative care; or

''(ii) treatment for cancer;

''(B) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

''(C) the State elects to treat as an exempted individual for purposes of paragraph (1).

''(d) APPLICATION OF PRIVACY RULES CLARIFICATION.—The Secretary shall clarify privacy requirements, including requirements under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), related to the sharing of data under subsection (b)(6) in the same manner as the Secretary is required under subparagraph (J) of section 1860D–4(c)(5) to clarify privacy requirements related to the sharing of data described in such subparagraph.

''(e) REPORTS.—

''(1) ANNUAL REPORTS.—A State operating a qualified drug management program shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D), beginning with such reports submitted for 2021, the following information:

''(A) The number of individuals enrolled under the State plan (or waiver of the State plan) who are enrolled under the program and the percentage of individuals enrolled under the State plan (or waiver) who are enrolled under such program.

''(B) The number of prescriptions for controlled substances that were dispensed per month during each such year per individual enrolled under the program, including the daily morphine milligram equivalents and the quantity prescribed for each such prescription.

''(C) The number of pharmacies filling prescriptions for controlled substances for individuals enrolled under such program.

''(D) The number of health care providers writing prescriptions for controlled substances (other than prescriptions for a refill) for individuals enrolled under such program.

''(E) Any other data that the Secretary may require.

''(F) Any report submitted by a managed care entity under subsection (f)(1)(B) with respect to the year involved.

For each such report for a year after 2021, the information described in this paragraph shall be provided in a manner that compares such information with respect to the prior calendar year to such information with respect to the second prior calendar year.

''(2) MACPAC REPORTS AND REVIEW.—Not later than two years after the date of the enactment of this section, the Medicaid and CHIP Payment and Access Commission (in this section referred to as 'MACPAC'), in consultation with the National Association of Medicaid Directors, pharmacy benefit managers, managed care organizations, health care providers (including pharmacists), beneficiary advocates, and other stakeholders, shall publish a report that includes—

''(A) best practices for operating drug management programs, based on a review of a representative sample of States administering such a program;

''(B) a summary of the experience of the appeals process under drug management programs operated by several States, such as the frequency at which individuals appealed the identification of being an at-risk individual, the frequency at which individuals appealed the selection of a health care provider or pharmacy under such a program, the timeframes for such appeals, a summary of the reasons for such appeals, and the design of such appeals processes;

''(C) a summary of trends and the effectiveness of qualified drug management programs operated under this section; and

''(D) recommendations to States on how improvements can be made with respect to the operation of such programs.

In reporting on State practices, the MACPAC shall consider how such programs have been implemented in rural areas, under fee-for-service as well as managed care arrangements, and the extent to which such programs have resulted in increased efficiencies to such States or to the Federal Government under this title.

''(3) REPORT ON PLAN FOR COORDINATED CARE.—Not later than January 1, 2021, each State

operating a qualified drug management program shall submit to the Administrator of the Centers for Medicare & Medicaid Services a report on how such State plans to provide coordinated care for individuals enrolled under the State plan (or waiver of the State plan) and—

''(A) who are enrolled under the program; or

''(B) who are enrolled with a managed care entity and enrolled under such a qualified drug management program operated by such entity.

''(f) APPLICABILITY TO MANAGED CARE ENTITIES.—

''(1) IN GENERAL.—With respect to any contract that a State enters into on or after January 1, 2020, with a managed care entity (as defined in section 1932(a)(1)(B)) pursuant to section 1903(m), the State shall, as a condition of the contract, require the managed care entity—

''(A) to operate a qualified drug management program (as defined in subsection (b)) for at-risk beneficiaries who are enrolled with such entity and identified by the managed care entity by means of application of paragraph (2);

''(B) to submit to the State an annual report on the matters described in subparagraphs (A) through (E) of subsection (e)(1); and

''(C) to submit to the State a list (and as necessary update such list) of individuals enrolled with such entity under the qualified drug management program operated by such entity under subparagraph (A) for purposes of allowing State plans for which medical assistance is paid on a fee-for-service basis to have access to such information.

''(2) APPLICATION.—For purposes of applying, with respect to a managed care entity—

''(A) under paragraph (1)(A)—

''(i) the definition of the term 'qualified drug management program' under subsection (b), other than paragraph (2)(D) of such subsection; and

''(ii) the provisions of paragraphs (1) and (2) of subsection (c); and

''(B) under paragraph (1)(B), the report requirements described in subparagraphs (A) through (E) of subsection (e)(1);

each reference in such subsection (b) and paragraphs of subsection (c) to 'a State' or 'the State'

(other than to 'a State plan' or 'the State plan') shall be deemed a reference to the managed care entity, each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the State plan (or waiver of the State plan) shall be deemed a reference to individuals enrolled with such entity, and each reference under such subsection, paragraphs, or subparagraphs to individuals enrolled under the qualified drug management program operated by the State shall be deemed a reference to individuals enrolled under the qualified drug management program operated by the managed care entity.

''(g) CONTROLLED SUBSTANCE DEFINED.—For purposes of this section, the term 'controlled substance' means a drug that is included in schedule II, III, or IV of section 202(c) of the Controlled Substances Act, or any combination thereof, as specified by the State.''.

(b) GUIDANCE ON AT-RISK POPULATION TRANSITIONING BETWEEN MEDICAID FFS AND MANAGED CARE.—Not later than October 1, 2019, the Secretary of Health and Human Services shall issue guidance for State Medicaid programs, with respect to individuals who are enrolled under a State plan (or waiver of such plan) under title XIX of the Social Security Act and under

a drug management program, for purposes of providing best practices—

(1) for transitioning, as applicable, such individuals from fee-for-service Medicaid (and such a program operated by the State) to receiving medical assistance under such title through a managed care entity (as defined in section 1932(a)(1)(B) of the Social Security Act) with a contract that with the State pursuant to section 1903(m) of such Act (and such a program operated by such entity); and

(2) for transitioning, as applicable, such individuals from receiving medical assistance under such title through a managed care entity (as defined in section 1932(a)(1)(B) of the Social Security Act) with a contract that with the State pursuant to section 1903(m) of such Act (and such a program operated by such entity) to fee-for-service Medicaid (and such a program operated by the State).

(c) GUIDANCE ON AT-RISK POPULATION TRANSITIONING TO MEDICARE.—

(1) IN GENERAL.—Not later than January 1, 2020, the Secretary of Health and Human Services, after consultation with the Federal Coordinated Health Care Office established under section 2602 of the Patient Protection and Affordable Care Act

(42 U.S.C. 1315b), shall issue guidance for State Medicaid programs, with respect to transitioning individuals, providing for—

(A) notification to be submitted by the State to the Centers for Medicare & Medicaid Services and such individuals of the status of such individuals as transitioning individuals;

(B) notification to such individuals about enrollment under a prescription drug plan under part D of such title or under a MA–PD plan under part C of such title;

(C) best practices for transitioning such individuals to such a plan; and

(D) best practices for coordination between the qualified drug management program (as described in section 1927A(b) of the Social Security Act, as added by subsection (a)) carried out by the State and a drug management program carried out under such a plan pursuant to section 1860D–4(c)(5) of the Social Security Act (42 U.S.C. 1395w–10(c)(5)).

(2) TRANSITIONING INDIVIDUALS.—For purposes of paragraph (1), a transitioning individual is an individual who, with respect to a month—

(A) is enrolled under the State plan (or waiver of the State plan) and under the qualified drug management program (as described in section 1927A(b) of the Social Security Act, as added by subsection (a)) carried out by the State; and

(B) is expected to become eligible for the Medicare program under title XVIII of such Act during the subsequent 12-month period.

SEC. 105. MEDICAID DRUG REVIEW AND UTILIZATION.

(a) MEDICAID DRUG UTILIZATION REVIEW.—

(1) STATE PLAN REQUIREMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 101, is further amended—

(A) in paragraph (83), at the end, by striking ''and'';

(B) in paragraph (84), at the end, by striking the period and inserting ''; and''; and

(C) by inserting after paragraph (84) the following new paragraph:

''(85) provide that the State is in compliance with the drug review and utilization requirements under subsection (oo)(1).''.

(2) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 101, is further amended by adding at the end the following new subsection:

''(oo) DRUG REVIEW AND UTILIZATION REQUIREMENTS.—

''(1) IN GENERAL.—For purposes of subsection (a)(85), the drug review and utilization requirements under this subsection are, subject to paragraph (3) and beginning October 1, 2019, the following:

''(A) CLAIMS REVIEW LIMITATIONS.—

''(i) IN GENERAL.—The State has in place—

''(I) safety edits (as specified by the State) for subsequent fills for opioids and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the State plan (or under a waiver of the State plan) is prescribed a subsequent fill of opioids in excess of any limitation that may be identified by the State;

''(II) safety edits (as specified by the State) on the maximum daily morphine equivalent that can be prescribed to an individual enrolled under the State plan (or under a waiver of the State plan) for treatment of chronic pain and a claims review automated process (as designed and implemented by the State) that indicates when an individual enrolled under the plan (or waiver) is prescribed the morphine equivalent for such treatment in excess of any limitation that may be identified by the State; and

''(III) a claims review automated process (as designed and implemented by the State) that monitors when an individual enrolled under the State plan (or under a waiver of the State plan) is concurrently prescribed opioids and—

''(aa) benzodiazepines; or

''(bb) antipsychotics.

''(ii) MANAGED CARE ENTITIES.—The State requires each managed care entity

(as defined in section 1932(a)(1)(B)) with respect to which the State has a contract under section 1903(m) or under section 1905(t)(3) to have in place, subject to paragraph (3), with respect to individuals who are eligible for medical assistance under the State plan (or under a waiver of the State plan) and who are enrolled with the entity, the limitations described in subclauses (I) and (II) of clause (i) and a claims review automated process described in subclause (III) of such clause.

''(iii) RULES OF CONSTRUCTION.—Nothing in this subparagraph may be construed as prohibiting a State or managed care entity from designing and implementing a claims review automated process under this subparagraph that provides for prospective or retrospective reviews of claims. Nothing in this subparagraph shall be understood as prohibiting the exercise of clinical judgment from a provider enrolled as a participating provider in a State plan (or waiver of the State plan) or contracting with a managed care entity re-

garding the best items and services for an individual enrolled under such State plan (or waiver).

''(B) PROGRAM TO MONITOR ANTIPSYCHOTIC MEDICATIONS BY CHILDREN.—The State has in place a program (as designed and implemented by the State) to monitor and manage the appropriate use of antipsychotic medications by children enrolled under the State plan (or under a waiver of the State plan) and submits annually to the Secretary such information as the Secretary may require on activities carried out under such program for individuals not more than the age of 18 years generally and children in foster care specifically.

''(C) FRAUD AND ABUSE IDENTIFICATION.—The State has in place a process (as designed and implemented by the State) that identifies potential fraud or abuse of controlled substances by individuals enrolled under the State plan (or under a waiver of the State plan), health care providers prescribing drugs to individuals so enrolled, and pharmacies dispensing drugs to individuals so enrolled.

''(D) REPORTS.—The State shall include in the annual report submitted to the Secretary under section 1927(g)(3)(D) information on the limitations, requirement, program, and processes applied by the State under subparagraphs (A) through (C) in accordance with such manner and time as specified by the Secretary.

''(E) CLARIFICATION.—Nothing shall prevent a State from satisfying the requirement—

''(i) described in subparagraph (A) by having safety edits or a claims review automated process described in such subparagraph that was in place before October 1, 2019;

''(ii) described in subparagraph (B) by having a program described in such subparagraph that was in place before such date; or

''(iii) described in subparagraph (C) by having a process described in such subparagraph that was in place before such date.

''(2) ANNUAL REPORT BY SECRETARY.—For each fiscal year beginning with fiscal year 2020, the Secretary shall submit to Congress a report on the

most recent information submitted by States under paragraph (1)(D).

''(3) EXCEPTIONS.—

''(A) CERTAIN INDIVIDUALS EXEMPTED.—The drug review and utilization requirements under this subsection shall not apply with respect to an individual who—

''(i) is receiving—

''(I) hospice or palliative care; or

''(II) treatment for cancer;

''(ii) is a resident of a long-term care facility, of a facility described in section 1905(d), or of another facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy; or

''(iii) the State elects to treat as exempted from such requirements.

''(B) EXCEPTION RELATING TO ENSURING ACCESS.—In order to ensure reasonable access to health care, the Secretary shall waive the drug review and utilization requirements under this subsection, with respect to a State, in the case of natural disasters and similar situations, and in the case of the provision of emergency

services (as defined for purposes of section 1860D–4(c)(5)(D)(ii)(II)).''.

(3) MANAGED CARE ENTITIES.—Section 1932 of the Social Security Act (42 U.S.C. 1396u–2) is amended by adding at the end the following new subsection:

''(i) DRUG UTILIZATION REVIEW ACTIVITIES AND REQUIREMENTS.—Beginning not later than October 1, 2019, each contract under a State plan with a managed care entity (other than a primary care case manager) under section 1903(m) shall provide that the entity is in compliance with the applicable provisions of section 438.3(s)(2) of title 42 of the Code of Federal Regulations, section 483.3(s)(4)) of such title, and section 483.3(s)(5) of such title, as such provisions were in effect on March 31, 2018.''.

(b) IDENTIFYING AND ADDRESSING INAPPROPRIATE PRESCRIBING AND BILLING PRACTICES UNDER MEDICAID.—

(1) IN GENERAL.—Section 1927(g) of the Social Security Act (42 U.S.C. 1396r–8(g)) is amended—

(A) in paragraph (1)(A)—

(i) by striking ''of section 1903(i)(10)(B)'' and inserting ''of section 1902(a)(54)'';

(ii) by striking '', by not later than January 1, 1993,'';

(iii) by inserting after ''gross overuse,'' the following: ''excessive utilization,''; and

(iv) by striking ''or inappropriate or medically unnecessary care'' and inserting ''inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization''; and

(B) in paragraph (2)(B)—

(i) by inserting after ''gross overuse,'' the following: ''excessive utilization,''; and

(ii) by striking ''or inappropriate or medically unnecessary care'' and inserting ''inappropriate or medically unnecessary care, or prescribing or billing practices that indicate abuse or excessive utilization''.

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect with respect to

retrospective drug use reviews conducted on or after October 1, 2020.

SEC. 106. GUIDANCE TO IMPROVE CARE FOR INFANTS WITH NEONATAL ABSTINENCE SYNDROME AND THEIR MOTHERS; GAO STUDY ON GAPS IN MEDICAID COVERAGE FOR PREGNANT AND POSTPARTUM WOMEN WITH SUBSTANCE USE DISORDER.

(a) GUIDANCE.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall issue guidance to improve care for infants with neonatal abstinence syndrome and their families. Such guidance shall include—

(1) the types of services, including post-discharge services and parenting supports, for families of babies with neonatal abstinence syndrome that States may cover under the Medicaid program under title XIX of the Social Security Act;

(2) best practices from States with respect to innovative or evidenced-based payment models that focus on prevention, screening, treatment, plans of safe care, and post-discharge services for mothers and fathers with substance use disorders and babies with neonatal abstinence syndrome that improve care and clinical outcomes;

(3) recommendations for States on available financing options under the Medicaid program under title XIX of such Act and under the Children's Health Insurance Program under title XXI of such Act for Children's Health Insurance Program Health Services Initiative funds for parents with substance use disorders, infants with neonatal abstinence syndrome, and home visiting services; and

(4) guidance and technical assistance to State Medicaid agencies regarding additional flexibilities and incentives related to screening, prevention, and post-discharge services, including parenting supports.

(b) GAO STUDY.—Not later than one year after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study, and submit to Congress a report, addressing gaps in coverage for pregnant women with substance use disorder under the Medicaid program under title XIX of the Social Security Act, and gaps in coverage for postpartum women with substance use disorder who had coverage during their pregnancy under the Medicaid program under such title.

SEC. 107. MEDICAID HEALTH HOMES FOR OPIOID-USE-DISORDER MEDICAID ENROLLEES.

(a) EXTENSION OF ENHANCED FMAP FOR CERTAIN HEALTH HOMES FOR INDIVIDUALS WITH SUBSTANCE USE DISORDERS.—Section 1945 of the Social Security Act (42 U.S.C. 1396w–4) is amended—

(1) in subsection (c)—

(A) in paragraph (1), by inserting ''subject to paragraph (4),'' after ''except that,''; and

(B) by adding at the end the following new paragraph:

''(4) SPECIAL RULE RELATING TO SUBSTANCE USE DISORDER HEALTH HOMES.—

''(A) IN GENERAL.—In the case of a State with an SUD-focused State plan amendment approved by the Secretary on or after October 1, 2018, the Secretary may, at the request of the State, extend the application of the Federal medical assistance percentage described in paragraph (1) to payments for the provision of health home services to SUD-eligible individuals under such State plan amendment, in addition to the first 8 fiscal year quarters the State plan amendment is in effect, for the subsequent 2 fiscal year quarters that the State plan amendment is in effect. Nothing in this section shall

be construed as prohibiting a State with a State plan amendment that is approved under this section and that is not an SUD-focused State plan amendment from additionally having approved on or after such date an SUD-focused State plan amendment under this section, including for purposes of application of this paragraph.

''(B) REPORT REQUIREMENTS.—In the case of a State with an SUD-focused State plan amendment for which the application of the Federal medical assistance percentage has been extended under subparagraph (A), such State shall, at the end of the period of such State plan amendment, submit to the Secretary a report on the following, with respect to SUD-eligible individuals provided health home services under such State plan amendment:

''(i) The quality of health care provided to such individuals, with a focus on outcomes relevant to the recovery of each such individual.

''(ii) The access of such individuals to health care.

''(iii) The total expenditures of such individuals for health care.

For purposes of this subparagraph, the Secretary shall specify all applicable measures for determining quality, access, and expenditures.

''(C) BEST PRACTICES.—Not later than October 1, 2020, the Secretary shall make publicly available on the Internet website of the Centers for Medicare & Medicaid Services best practices for designing and implementing an SUD-focused State plan amendment, based on the experiences of States that have State plan amendments approved under this section that include SUD-eligible individuals.

''(D) DEFINITIONS.—For purposes of this paragraph:

''(i) SUD-ELIGIBLE INDIVIDUALS.—The term 'SUD-eligible individual' means, with respect to a State, an individual who satisfies all of the following:

''(I) The individual is an eligible individual with chronic conditions.

''(II) The individual is an individual with a substance use disorder.

''(III) The individual has not previously received health home services under any other State plan amendment approved for the State under this section by the Secretary.

''(ii) SUD-FOCUSED STATE PLAN AMENDMENT.—The term 'SUD-focused State plan amendment' means a State plan amendment under this section that is designed to provide health home services primarily to SUD-eligible individuals.''.

(b) REQUIREMENT FOR STATE MEDICAID PLANS TO PROVIDE COVERAGE FOR MEDICATION-ASSISTED TREATMENT.—

(1) REQUIREMENT FOR STATE MEDICAID PLANS TO PROVIDE COVERAGE FOR MEDICATION-ASSISTED TREATMENT.—Section 1902(a)(10)(A) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)) is amended, in the matter preceding clause (i), by striking ''and (28)'' and inserting ''(28), and (29)''.

(2) INCLUSION OF MEDICATION-ASSISTED TREATMENT AS MEDICAL ASSISTANCE.—Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) is amended—

(A) in paragraph (28), by striking ''and'' at the end;

(B) by redesignating paragraph (29) as paragraph (30); and

(C) by inserting after paragraph (28) the following new paragraph:

''(29) subject to paragraph (2) of subsection (ee), for the period beginning October 1, 2020, and ending September 30, 2025, medication-assisted treatment (as defined in paragraph (1) of such subsection); and''.

(3) MEDICATION-ASSISTED TREATMENT DEFINED; WAIVERS.—Section 1905 of the Social Security Act (42 U.S.C. 1396d) is amended by adding at the end the following new subsection:

''(ee) MEDICATION-ASSISTED TREATMENT.—

''(1) DEFINITION.—For purposes of subsection (a)(29), the term 'medication-assisted treatment'—

''(A) means all drugs approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355), including methadone, and all biological products licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) to treat opioid use disorders; and

''(B) includes, with respect to the provision of such drugs and biological products, counseling services and behavioral therapy.

''(2) EXCEPTION.—The provisions of paragraph (29) of subsection (a) shall not apply with respect to a State for the period specified in such paragraph, if before the beginning of such period the State certifies to the satisfaction of the Secretary that implementing such provisions statewide for all individuals eligible to enroll in the State plan (or waiver of the State plan) would not be feasible by reason of a shortage of qualified providers of medication-assisted treatment, or facilities providing such treatment, that will contract with the State or a managed care entity with which the State has a contract under section 1903(m) or under section 1905(t)(3).''.

(4) EFFECTIVE DATE.—

(A) IN GENERAL.—Subject to subparagraph (B), the amendments made by this subsection shall apply with respect to medical assistance provided on or after October 1, 2020, and before October 1, 2025.

(B) EXCEPTION FOR STATE LEGISLATION.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396

et seq.) that the Secretary of Health and Human Services determines requires State legislation in order for the respective plan to meet any requirement imposed by the amendments made by this subsection, the respective plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

TITLE II—MEDICARE PROVISIONS TO ADDRESS THE OPIOID CRISIS

SEC. 201. AUTHORITY NOT TO APPLY CERTAIN MEDICARE TELEHEALTH REQUIREMENTS IN THE CASE OF CERTAIN TREATMENT OF A SUBSTANCE USE DISORDER OR CO-OCCURRING MENTAL HEALTH DISORDER.

Section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended—

(1) in paragraph (2)(B)(i), by inserting ''and paragraph (7)(E)'' after ''Subject to clause (ii)''; and

(2) by adding at the end the following new paragraphs:

''(7) AUTHORITY NOT TO APPLY CERTAIN REQUIREMENTS IN THE CASE OF CERTAIN TREATMENT OF SUBSTANCE USE DISORDER OR CO-OCCURRING MENTAL HEALTH DISORDER.—

''(A) IN GENERAL.—For purposes of payment under this subsection, in the case of telehealth services described in subparagraph (C) furnished on or after January 1, 2020, to an eligible beneficiary (as defined in subparagraph (F)) for the treatment of a substance use dis-

order or a mental health disorder that is co-occurring with a substance use disorder, the Secretary is authorized to, through rulemaking, not apply any of the requirements described in subparagraph (B).

''(B) REQUIREMENTS DESCRIBED.—For purposes of this paragraph, the requirements described in this subparagraph are any of the following:

''(i) Qualifications for an originating site under paragraph (4)(C)(ii).

''(ii) Geographic limitations under paragraph (4)(C)(i).

''(C) TELEHEALTH SERVICES DESCRIBED.—For purposes of this paragraph, the telehealth services described in this subparagraph are services that are both telehealth services and identified by the Secretary, through rulemaking, as services that are the most commonly furnished (as defined by the Secretary) under this part to individuals diagnosed with a substance use disorder or a mental health disorder that is co-occurring with a substance use disorder.

"(D) CLARIFICATION.—Nothing in this paragraph shall be construed as limiting or otherwise affecting the authority of the Secretary to limit or eliminate the non-application pursuant to this paragraph of any of the requirements under subparagraph (B).

"(E) TREATMENT OF ORIGINATING SITE FACILITY FEE.—No facility fee shall be paid under paragraph (2)(B) to an originating site with respect to a telehealth service described in subparagraph (B) for which payment is made under this subsection by reason of the non-application of a requirement described in subparagraph (B) pursuant to this paragraph if payment for such service would not otherwise be permitted under this subsection if such requirement were applied.

"(F) ELIGIBLE BENEFICIARY DEFINED.—For purposes of this paragraph, the term 'eligible beneficiary' means an individual who—

"(i) is entitled to, or enrolled for, benefits under part A and enrolled for benefits under this part;

"(ii) has a diagnosis for a substance use disorder; and

''(iii) meets such other criteria as the Secretary determines appropriate.

''(G) REPORT.—Not later than 5 years after the date of the enactment of this paragraph, the Secretary shall submit to Congress a report on the impact of any non-application under this paragraph of any of the requirements described in subparagraph (B) on

''(i) the utilization of health care services related to substance use disorder, such as behavioral health services and emergency department visits; and

''(ii) health outcomes related to substance use disorder, such as substance use overdose deaths.

''(H) FUNDING.—For purposes of carrying out this paragraph, in addition to funds otherwise available, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, of $3,000,000 to the Centers for Medicare & Medicaid Services Program Management Account to remain available until expended.

''(8) RULE OF CONSTRUCTION.—Nothing in this subsection may be construed as waiving require-

ments under this title to comply with applicable State law, including State licensure requirements.''.

SEC. 202. ENCOURAGING THE USE OF NON-OPIOID ANALGESICS FOR THE MANAGEMENT OF POST-SURGICAL PAIN.

Section 1833(t)(6) of the Social Security Act (42 U.S.C. 1395l(t)(6)) is amended—

(1) in subparagraph (C)(i), by inserting ''or, in the case of an eligible non-opioid analgesic (as defined in subparagraph (J)), during a period of 5 years,'' after ''3 years,''; and

(2) by adding at the end the following new subparagraph:

''(J) ELIGIBLE NON-OPIOID ANALGESIC DEFINED.—In this paragraph, the term 'eligible non-opioid analgesic' means a drug or biological—

''(i) that is an analgesic that is not an opioid;

''(ii) that demonstrated substantial clinical improvement; and

''(iii) for which payment—

''(I) as an outpatient hospital service under this part was not being

made as of the date of the enactment of this subparagraph; or

''(II) was being made under this paragraph as of such date.''.

SEC. 203. REQUIRING A REVIEW OF CURRENT OPIOID PRESCRIPTIONS FOR CHRONIC PAIN AND SCREENING FOR OPIOID USE DISORDER TO BE INCLUDED IN THE WELCOME TO MEDICARE INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) IN GENERAL.—Section 1861(ww) of the Social Security Act (42 U.S.C. 1395x(ww)) is amended—

(1) in paragraph (1), by inserting ''and a review of current opioid prescriptions and screening for opioid use disorder (as defined in paragraph (4)),'' before ''but does not include''; and

(2) by adding at the end the following new paragraph:

''(4)(A) For purposes of paragraph (1), the term 'a review of current opioid prescriptions and screening for opioid use disorder' means, with respect to an individual—

''(i) a review by a physician or qualified non-physician practitioner of all current prescriptions of the individual; and

''(ii) in the case of an individual determined by the review of a physician or qualified non-physician practitioner under subparagraph (A) to have a current prescription for opioids for chronic pain that has been prescribed for a minimum period of time (as specified by the Secretary)—

''(I) a review by the physician or practitioner of the potential risk factors to the individual for opioid use disorder;

''(II) an evaluation by the physician or practitioner of pain of the individual;

''(III) the provision of information regarding non-opioid treatment options for the treatment and management of any chronic pain of the individual; and

''(IV) if determined necessary by the physician or practitioner based on the results of the review and evaluation conducted as described in this paragraph, an appropriate referral by the physician or practitioner for additional treatment.

''(B) For purposes of this paragraph, the term 'qualified non-physician practitioner' means a physician assistant, nurse practitioner, or certified clinical nurse specialist.''.

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to initial preventive physical examinations furnished on or after January 1, 2020.

SEC. 204. MODIFICATION OF PAYMENT FOR CERTAIN OUTPATIENT SURGICAL SERVICES.

(a) FREEZE OF PAYMENT FOR CERTAIN SERVICES FURNISHED IN AMBULATORY SURGICAL CENTERS.—Section 1833(i)(2) of the Social Security Act (42 U.S.C. 1395l(i)(2)) is amended by adding at the end the following new subparagraph:

''(F)(i) With respect to a targeted procedure (as defined in clause (ii)) furnished during 2020 or a subsequent year (before 2024) to an individual in an ambulatory surgical center, the payment amount for such procedure that would otherwise be determined under the revised payment system under subparagraph (D), without application of this subparagraph, shall be equal to the payment amount for such procedure furnished in 2016.

''(ii) For purposes of clause (i), the term 'targeted procedure' means a procedure to which Healthcare Common Procedure Coding System 62310 (or, for years beginning after 2016, 62321), 62311 (or, for years beginning after 2016, 62323),

62264, 64490, 64493, or G0260 (or any successor code) applies.

''(iii) This subparagraph shall not be applied in a budget-neutral manner.''.

(b) DATA COLLECTION.—

(1) IN GENERAL.—The Comptroller General shall collect data relating to the cost differential between targeted procedures (as defined in section 1833(i)(2)(F)(ii) of the Social Security Act, as added by subsection (a)) that are performed in a hospital operating room and such procedures that are performed in an office setting within a hospital in order to determine whether such procedures are being properly coded for claims, based on setting, for payment under section 1833(i)(2)(D) of the Social Security Act (42 U.S.C. 1395l(i)(2)(D)) and to determine if further changes are needed in the classification system for covered outpatient department services (as described in section 1833(t)(2)(A) of the Social Security Act (42 U.S.C. 1395l(t)(2)(A)).

(2) REPORT.—Not later than 4 years after the date of the enactment of this Act, the Comptroller General shall submit a report to the Committee on Energy and Commerce and the Committee on Ways

and Means of the House of Representatives and the Committee on Finance of the Senate containing—

(A) a determination of whether procedures described in paragraph (1) are being properly coded for claims, based on setting, for payment under section 1833(i)(2)(D) of the Social Security Act (42 U.S.C. 1395l(i)(2)(D)); and

(B) recommendations on any changes the Comptroller General determines are needed in the classification system for covered outpatient department services (as described in section 1833(t)(2)(A) of the Social Security Act (42 U.S.C. 1395l(t)(2)(A)).

(c) STUDY.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall conduct a study and submit to Congress a report on the extent to which procedures described in section 1833(i)(2)(F)(ii) of the Social Security Act, as added by subsection (a), are effective at preventing the need for opioids for individuals furnished such procedures.

SEC. 205. REQUIRING E-PRESCRIBING FOR COVERAGE OF COVERED PART D CONTROLLED SUBSTANCES.

(a) IN GENERAL.—Section 1860D–4(e) of the Social Security Act (42 U.S.C. 1395w–104(e)) is amended by adding at the end the following:

"(7) REQUIREMENT OF E-PRESCRIBING FOR CONTROLLED SUBSTANCES.—

"(A) IN GENERAL.—Subject to subparagraph (B), a prescription for a covered part D drug under a prescription drug plan (or under an MA–PD plan) for a schedule II, III, IV, or V controlled substance shall be transmitted by a health care practitioner electronically in accordance with an electronic prescription drug program that meets the requirements of paragraph (2).

"(B) EXCEPTION FOR CERTAIN CIRCUMSTANCES.—The Secretary shall, pursuant to rulemaking, specify circumstances with respect to which the Secretary may waive the requirement under subparagraph (A), with respect to a covered part D drug, including in the case of—

''(i) a prescription issued when the practitioner and dispenser are the same entity;

''(ii) a prescription issued that cannot be transmitted electronically under the most recently implemented version of the National Council for Prescription Drug Programs SCRIPT Standard;

''(iii) a prescription issued by a practitioner who has received a waiver or a renewal thereof for a specified period determined by the Secretary, not to exceed one year, from the requirement to use electronic prescribing, pursuant to a process established by regulation by the Secretary, due to demonstrated economic hardship, technological limitations that are not reasonably within the control of the practitioner, or other exceptional circumstance demonstrated by the practitioner;

''(iv) a prescription issued by a practitioner under circumstances in which, notwithstanding the practitioner's ability to submit a prescription electronically as required by this subsection, such practitioner

reasonably determines that it would be impractical for the individual involved to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the individual's medical condition involved;

''(v) a prescription issued by a practitioner allowing for the dispensing of a non-patient specific prescription pursuant to a standing order, approved protocol for drug therapy, collaborative drug management, or comprehensive medication management, in response to a public health emergency, or other circumstances where the practitioner may issue a non-patient specific prescription;

''(vi) a prescription issued by a practitioner prescribing a drug under a research protocol;

''(vii) a prescription issued by a practitioner for a drug for which the Food and Drug Administration requires a prescription to contain elements that are not able to be included in electronic prescribing, such as a drug with risk evaluation and

mitigation strategies that include elements to assure safe use; and

''(viii) a prescription issued by a practitioner for an individual who—

''(I) receives hospice care under this title; or

''(II) is a resident of a skilled nursing facility (as defined in section 1819(a)), or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B), for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, as determined by the Secretary in accordance with this paragraph.

''(C) DISPENSING.—Nothing in this paragraph shall be construed as requiring a sponsor of a prescription drug plan under this part, MA organization offering an MA–PD plan under part C, or a pharmacist to verify that a practitioner, with respect to a prescription for a covered part D drug, has a waiver (or is otherwise exempt) under subparagraph (B) from the re-

quirement under subparagraph (A). Nothing in this paragraph shall be construed as affecting the ability of the plan to cover or the pharmacists' ability to continue to dispense covered part D drugs from otherwise valid written, oral or fax prescriptions that are consistent with laws and regulations. Nothing in this paragraph shall be construed as affecting the ability of the beneficiary involved to designate a particular pharmacy to dispense a prescribed drug to the extent consistent with the requirements under subsection (b)(1) and under this paragraph.

''(D) ENFORCEMENT.—The Secretary shall, pursuant to rulemaking, have authority to enforce and specify appropriate penalties for non-compliance with the requirement under subparagraph (A).''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to coverage of drugs prescribed on or after January 1, 2021.

SEC. 206. REQUIRING PRESCRIPTION DRUG PLAN SPONSORS UNDER MEDICARE TO ESTABLISH DRUG MANAGEMENT PROGRAMS FOR AT-RISK BENEFICIARIES.

Section 1860D–4(c) of the Social Security Act (42 U.S.C. 1395w–104(c)) is amended—

(1) in paragraph (1), by inserting after subparagraph (E) the following new subparagraph:

"(F) With respect to plan years beginning on or after January 1, 2021, a drug management program for at-risk beneficiaries described in paragraph (5)."; and

(2) in paragraph (5)(A), by inserting "(and for plan years beginning on or after January 1, 2021, a PDP sponsor shall)" after "A PDP sponsor may".

SEC. 207. MEDICARE COVERAGE OF CERTAIN SERVICES FURNISHED BY OPIOID TREATMENT PROGRAMS.

(a) COVERAGE.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (FF), by striking at the end "and";

(2) in subparagraph (GG), by inserting at the end "; and"; and

(3) by adding at the end the following new subparagraph:

''(HH) opioid use disorder treatment services (as defined in subsection (jjj)).''.

(b) OPIOID USE DISORDER TREATMENT SERVICES AND OPIOID TREATMENT PROGRAM DEFINED.—Section 1861 of the Social Security Act is amended by adding at the end the following new subsection:

''(jjj) OPIOID USE DISORDER TREATMENT SERVICES; OPIOID TREATMENT PROGRAM.—

''(1) OPIOID USE DISORDER TREATMENT SERVICES.—The term 'opioid use disorder treatment services' means items and services that are furnished by an opioid treatment program for the treatment of opioid use disorder, including—

''(A) opioid agonist and antagonist treatment medications (including oral, injected, or implanted versions) that are approved by the Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act for use in the treatment of opioid use disorder;

''(B) dispensing and administration of such medications, if applicable;

''(C) substance use counseling by a professional to the extent authorized under State law to furnish such services;

''(D) individual and group therapy with a physician or psychologist (or other mental health professional to the extent authorized under State law);

''(E) toxicology testing, and

''(F) other items and services that the Secretary determines are appropriate (but in no event to include meals or transportation).

''(2) OPIOID TREATMENT PROGRAM.—The term 'opioid treatment program' means an entity that is opioid treatment program (as defined in section 8.2 of title 42 of the Code of Federal Regulations, or any successor regulation) that—

''(A) is enrolled under section 1866(j);

''(B) has in effect a certification by the Substance Abuse and Mental Health Services Administration for such a program;

''(C) is accredited by an accrediting body approved by the Substance Abuse and Mental Health Services Administration; and

''(D) meets such additional conditions as the Secretary may find necessary to ensure—

''(i) the health and safety of individuals being furnished services under such program; and

''(ii) the effective and efficient furnishing of such services.''.

(c) PAYMENT.—

(1) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(A) by striking ''and (BB)'' and inserting ''(BB)''; and

(B) by inserting before the semicolon at the end the following '', and (CC) with respect to opioid use disorder treatment services furnished during an episode of care, the amount paid shall be equal to the amount payable under section 1834(w) less any copayment required as specified by the Secretary''.

(2) PAYMENT DETERMINATION.—Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

''(w) OPIOID USE DISORDER TREATMENT SERVICES.—

''(1) IN GENERAL.—The Secretary shall pay to an opioid treatment program (as defined in paragraph (2) of section 1861(jjj)) an amount that is equal to 100 percent of a bundled payment under

this part for opioid use disorder treatment services (as defined in paragraph (1) of such section) that are furnished by such program to an individual during an episode of care (as defined by the Secretary) beginning on or after January 1, 2020. The Secretary shall ensure, as determined appropriate by the Secretary, that no duplicative payments are made under this part or part D for items and services furnished by an opioid treatment program.

''(2) CONSIDERATIONS.—The Secretary may implement this subsection through one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine appropriate. In developing such bundles, the Secretary may consider payment rates paid to opioid treatment programs for comparable services under State plans under title XIX or under the TRICARE program under chapter 55 of title 10 of the United States Code.

''(3) ANNUAL UPDATES.—The Secretary shall provide an update each year to the bundled payment amounts under this subsection.''.

(d) INCLUDING OPIOID TREATMENT PROGRAMS AS MEDICARE PROVIDERS.—Section 1866(e) of the Social Security Act (42 U.S.C. 1395cc(e)) is amended—

(1) in paragraph (1), by striking at the end ''and'';

(2) in paragraph (2), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following new paragraph:

''(3) opioid treatment programs (as defined in paragraph (2) of section 1861(jjj)), but only with respect to the furnishing of opioid use disorder treatment services (as defined in paragraph (1) of such section).''.

TITLE III—OTHER HEALTH PROVISIONS TO ADDRESS THE OPIOID CRISIS

SEC. 301. CLARIFYING FDA REGULATION OF NON-ADDICTIVE PAIN AND ADDICTION THERAPIES.

(a) PUBLIC MEETINGS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall hold not less than one public meeting to address the challenges and barriers of developing

non-addictive medical products intended to treat pain or addiction, which may include—

(1) the application of novel clinical trial designs (consistent with section 3021 of the 21st Century Cures Act (Public Law 114–255)), use of real world evidence (consistent with section 505F of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355g)), and use of patient experience data (consistent with section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c)) for the development of non-addictive medical products intended to treat pain or addiction; and

(2) the application of eligibility criteria under sections 506 and 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356, 360e–3) for non-addictive medical products intended to treat pain or addiction.

(b) GUIDANCE.—Not later than one year after the public meetings are conducted under subsection (a) the Secretary shall issue one or more final guidance documents, or update existing guidance documents, to help address challenges to developing non-addictive medical products to treat pain or addiction. Such guidance documents shall include information regarding—

(1) how the Food and Drug Administration may apply sections 506 and 515B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356, 360e–3) to non-addictive medical products intended to treat pain or addiction, including the circumstances under which the Secretary—

(A) may apply the eligibility criteria under such sections 506 and 515B to non-opioid or non-addictive medical products intended to treat pain or addiction;

(B) considers the risk of addiction of controlled substances approved to treat pain when establishing unmet medical need; and

(C) considers pain, pain control, or pain management in assessing whether a disease or condition is a serious or life-threatening disease or condition; and

(2) the methods by which sponsors may evaluate acute and chronic pain, endpoints for non-addictive medical products intended to treat pain, the manner in which endpoints and evaluations of efficacy will be applied across and within review divisions, taking into consideration the etiology of the underlying disease, and the manner in which spon-

sors may use surrogate endpoints, intermediate endpoints, and real world evidence.

(c) MEDICAL PRODUCT DEFINED.—In this section, the term ''medical product'' means a drug (as defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1))), biological product (as defined in section 351(i) of the Public Health Service Act (42 U.S.C. 262(i))), or device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h))).

SEC. 302. SURVEILLANCE AND TESTING OF OPIOIDS TO PREVENT FENTANYL DEATHS.

(a) PUBLIC HEALTH LABORATORIES TO DETECT FENTANYL.—Part F of title III of the Public Health Service Act (42 U.S.C. 262 et seq.) is amended—

(1) in the heading of part F, by striking ''AND CLINICAL LABORATORIES'' and inserting '', CLINICAL LABORATORIES, AND PUBLIC HEALTH LABORATORIES''; and

(2) by adding at the end the following new subpart:

"Subpart 4—Public Health Laboratories

"SEC. 355. PUBLIC HEALTH LABORATORIES TO DETECT FENTANYL.

''(a) IN GENERAL.—The Secretary shall establish a program to award grants to Federal, State, and local agencies to support the establishment or operation of public health laboratories to detect fentanyl, its analogues, and other synthetic opioids, as described in subsection (b).

''(b) STANDARDS.—The Secretary, in consultation with the Director of the National Institute of Standards and Technology, shall—

''(1) develop standards for safely and effectively handling and testing fentanyl, its analogues, and other synthetic opioids;

''(2) develop fentanyl and fentanyl analog reference materials and quality control standards and protocols to calibrate instrumentation for clinical diagnostics and postmortem surveillance; and

''(3) include in the standards developed pursuant to paragraph (1) procedures for encountering new and emerging synthetic opioid formulations and reporting those findings to other Federal, State, and local public health laboratories.

''(c) LABORATORIES.—The Secretary shall require grantees under subsection (a) to—

''(1) follow the standards established under subsection (b) and be capable of providing systematic and routine laboratory testing of drugs for the purposes of obtaining and disseminating public health information to Federal, State, and local public health officials, laboratories, and other entities the Secretary deems appropriate;

''(2) work with law enforcement agencies and public health authorities, as feasible, to develop real-time information on the purity and movement of fentanyl, its analogues, and other synthetic opioids;

''(3) assist State and local law enforcement agencies in testing seized drugs when State and local forensic laboratories request additional assistance;

''(4) provide early warning information and advice to Federal, State, and local law enforcement agencies and public health authorities regarding potential significant changes in the supply of fentanyl, its analogues, and other synthetic opioids;

''(5) provide biosurveillance for non-fatal exposures; and

''(6) provide diagnostic testing for non-fatal exposures of emergency personnel.

''(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appro-

priated $15,000,000 for each of fiscal years 2019 through 2023.''.

(b) ENHANCED FENTANYL SURVEILLANCE.—Title III of the Public Health Service Act is amended by inserting after section 317T of such Act (42 U.S.C. 247b–22) the following new section:

''SEC. 317U. ENHANCED FENTANYL SURVEILLANCE.

''(a) IN GENERAL.—The Director of the Centers for Disease Control and Prevention shall enhance its drug surveillance program by—

''(1) expanding its surveillance program to include all 50 States and the territories of the United States;

''(2) increasing and accelerating the collection of data on fentanyl, its analogues, and other synthetic opioids and new emerging drugs of abuse, including related overdose data from medical examiners and drug treatment admissions; and

''(3) utilizing available and emerging information on fentanyl, its analogues, and other synthetic opioids and new emerging drugs of abuse, including information from—

''(A) the National Drug Early Warning System;

''(B) State and local public health authorities; and

''(C) Federal, State, and local public health laboratories.

''(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $10,000,000 for each of fiscal years 2019 through 2023.''.

(c) PILOT PROGRAM FOR POINT-OF-USE TESTING OF ILLICIT DRUGS FOR DANGEROUS CONTAMINANTS.—Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following new section:

''SEC. 399V-7. PILOT PROGRAM FOR POINT-OF-USE TESTING OF ILLICIT DRUGS FOR DANGEROUS CONTAMINANTS.

''(a) IN GENERAL.—The Secretary shall—

''(1) establish a pilot program through which 5 State or local agencies conduct, in 5 States, point-of-use testing of illicit drugs for dangerous contaminants;

''(2) establish metrics to evaluate the success of the pilot program in reducing drug overdose rates; and

''(3) based on such metrics, conduct an annual evaluation of the pilot program and submit an annual report to the Congress containing the results of such evaluation.

''(b) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $5,000,000 for each of fiscal years 2019 through 2023.''.

SEC. 303. ALLOWING FOR MORE FLEXIBILITY WITH RESPECT TO MEDICATION-ASSISTED TREATMENT FOR OPIOID USE DISORDERS.

(a) CONFORMING APPLICABLE NUMBER.—Subclause (II) of section 303(g)(2)(B)(iii) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(B)(iii)) is amended to read as follows:

''(II) The applicable number is—

''(aa) 100 if, not sooner than 1 year after the date on which the practitioner submitted the initial notification, the practitioner submits a second notification to the Secretary of the need and intent of the practitioner to treat up to 100 patients;

''(bb) 100 if the practitioner holds additional credentialing, as defined in section 8.2 of

title 42, Code of Federal Regulations (or successor regulations); or

''(cc) 100 if the practitioner provides medication-assisted treatment (MAT) using covered medications (as such terms are defined in section 8.2 of title 42, Code of Federal Regulations (or successor regulations)) in a qualified practice setting (as described in section 8.615 of title 42, Code of Federal Regulations (or successor regulations)).''.

(b) ELIMINATING ANY TIME LIMITATION FOR NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS TO BECOME QUALIFYING PRACTITIONERS.—Clause (iii) of section 303(g)(2)(G) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)) is amended—

(1) in subclause (I), by striking ''or'' at the end; and

(2) by amending subclause (II) to read as follows:

''(II) a qualifying other practitioner, as defined in clause (iv), who is a nurse practitioner or physician assistant; or''.

(c) IMPOSING A TIME LIMITATION FOR CLINICAL NURSE SPECIALISTS, CERTIFIED REGISTERED NURSE ANESTHETISTS, AND CERTIFIED NURSE MIDWIFES TO

BECOME QUALIFYING PRACTITIONERS.—Clause (iii) of section 303(g)(2)(G) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)), as amended by subsection (b), is further amended by adding at the end the following:

''(III) for the period beginning on October 1, 2018, and ending on October 1, 2023, a qualifying other practitioner, as defined in clause (iv), who is a clinical nurse specialist, certified registered nurse anesthetist, or certified nurse midwife.''.

(d) DEFINITION OF QUALIFYING OTHER PRACTITIONER.—Section 303(g)(2)(G)(iv) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)(iv)) is amended by striking ''nurse practitioner or physician assistant'' each place it appears and inserting ''nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, or physician assistant''.

(e) REPORT BY SECRETARY.—Not later than two years after the date of the enactment of this Act, the Secretary of Health and Human Services, in consultation with the Drug Enforcement Administration, shall submit to Congress a report that assesses the care provided by qualifying practitioners (as defined in section 303(g)(2)(G)(iii) of the Controlled Substances Act (21 U.S.C. 823(g)(2)(G)(iii))) who are treating, in the case of physi-

cians, 100 or more patients, and in the case of qualifying practitioners who are not physicians, 30 or more patients. Such report shall include recommendations on future applicable patient number levels and limits. In preparing such report, the Secretary shall study, with respect to opioid use disorder treatment—

(1) the average frequency with which qualifying practitioners see their patients;

(2) the average frequency with which patients receive counseling, including the rates by which such counseling is provided by such a qualifying practitioner directly, or by referral;

(3) the average frequency with which random toxicology testing is administered;

(4) the average monthly patient caseload for each type of qualifying practitioner;

(5) the treatment retention rates for patients;

(6) overdose and mortality rates; and

(7) any available information regarding the diversion of drugs by patients receiving such treatment from such a qualifying practitioner.

TITLE IV—OFFSETS

SEC. 401. PROMOTING VALUE IN MEDICAID MANAGED CARE.

Section 1903(m) of the Social Security Act (42 U.S.C. 1396b(m)) is amended by adding at the end the following new paragraph:

''(7)(A) With respect to expenditures described in subparagraph (B) that are incurred by a State for any fiscal year after fiscal year 2020 (and before fiscal year 2025), in determining the pro rata share to which the United States is equitably entitled under subsection (d)(3), the Secretary shall substitute the Federal medical assistance percentage that applies for such fiscal year to the State under section 1905(b) (without regard to any adjustments to such percentage applicable under such section or any other provision of law) for the percentage that applies to such expenditures under section 1905(y).

''(B) Expenditures described in this subparagraph, with respect to a fiscal year to which subparagraph (A) applies, are expenditures incurred by a State for payment for medical assistance provided to individuals described in subclause (VIII) of section 1902(a)(10)(A)(i) by a managed care entity, or other specified entity (as defined in subparagraph (D)(iii)), that are treated as remittances because the State—

''(i) has satisfied the requirement of section 438.8 of title 42, Code of Federal Regulations (or any successor regulation), by electing—

''(I) in the case of a State described in subparagraph (C), to apply a minimum medical loss ratio (as defined in subparagraph (D)(ii)) that is equal to or greater than 85 percent; or

''(II) in the case of a State not described in subparagraph (C), to apply a minimum medical loss ratio that is equal to 85 percent; and

''(ii) recovered all or a portion of the expenditures as a result of the entity's failure to meet such ratio.

''(C) For purposes of subparagraph (B), a State described in this subparagraph is a State that as of May 31, 2018, applied a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in such subparagraph under the State plan under this title (or a waiver of the plan) that is equal to or greater than 85 percent.

''(D) For purposes of this paragraph:

''(i) The term 'managed care entity' means a medicaid managed care organization described in section 1932(a)(1)(B)(i).

''(ii) The term 'minimum medical loss ratio' means, with respect to a State, a minimum medical loss ratio (as calculated under subsection (d) of section 438.8 of title 42, Code of Federal Regulations (as in effect on June 1, 2018)) for payment for services provided by entities described in subparagraph (B) under the State plan under this title (or a waiver of the plan).

''(iii) The term 'other specified entity' means—

''(I) a prepaid inpatient health plan, as defined in section 438.2 of title 42, Code of Federal Regulations (or any successor regulation); and

''(II) a prepaid ambulatory health plan, as defined in such section (or any successor regulation).''.

SEC. 402. EXTENDING PERIOD OF APPLICATION OF MEDICARE SECONDARY PAYER RULES FOR INDIVIDUALS WITH END STAGE RENAL DISEASE.

Section 1862(b)(1)(C) of the Social Security Act (42 U.S.C. 1395y(b)(1)(C)) is amended—

(1) in the last sentence, by inserting ''and before January 1, 2020'' after ''date of enactment of the Balanced Budget Act of 1997''; and

(2) by adding at the end the following new sentence: ''Effective for items and services furnished on or after January 1, 2020 (with respect to periods beginning on or after July 1, 2018), clauses (i) and (ii) shall be applied by substituting '33-month' for '12-month' each place it appears.''.

SEC. 403. REQUIRING REPORTING BY GROUP HEALTH PLANS OF PRESCRIPTION DRUG COVERAGE INFORMATION FOR PURPOSES OF IDENTIFYING PRIMARY PAYER SITUATIONS UNDER THE MEDICARE PROGRAM.

Clause (i) of section 1862(b)(7)(A) of the Social Security Act (42 U.S.C. 1395y(b)(7)(A)) is amended to read as follows:

''(i) secure from the plan sponsor and plan participants such information as the Secretary shall specify for the purpose of identifying situations where the group health plan is or has been—

''(I) a primary plan to the program under this title; or

''(II) for calendar quarters beginning on or after January 1, 2020, a primary payer with respect to benefits relating to prescription drug coverage under part D; and''.